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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,978	02/10/2006	Jens-Peter Seher	PHDE030277US	7394

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EXAMINER	
SU, SUSAN SHAN	
ART UNIT	**PAPER NUMBER**
3761	
MAIL DATE	**DELIVERY MODE**
03/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,978	SEHER ET AL.	
	Examiner	Art Unit	
	SUSAN SU	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-10 and 12-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-10 and 12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 2-10 and 12-20 are pending, wherein Claims 2-10 are amended and Claims 12-20 are new. No new matter is added. All claims are examined on the merits.

Response to Arguments

1. Applicant's arguments filed December 2, 2008 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Wesseler does not address problems associated with point of care testing containers) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's arguments regarding Tingey's teachings against coating the *interior* walls of a slit in the closure means has no bearing on the claim examination because the original independent claim 1 clearly states "coated with polytetrafluoroethylene on one side that is accessible from *outside*," which is exactly what Tingey teaches.

Applicant argues that neither Wesseler nor Tingey discloses a fluid-receiving space. The Examiner respectfully disagrees. Under broad reasonable interpretation, the enlarged area adjacent the resilient check valve indeed "receives" fluid because the fluid has to pass through that space. The remaining claims 2-9 and 12 have been newly

amended to depend on Claim 10 instead of Claim 1 and therefore arguments drawn to these claims are moot because the rejections have yet to be presented.

Specification

Acknowledgement is made of amendments to the Specification and the Abstract. No new matter is added.

Claim Objections

2. Claims 8, 13, 15, & 16 are objected to because of the following informalities: typographical error. There is an extra “the” on line 5 of Claim 8. The word "defines" on line 5 of Claim 13 is misspelled. The word “closure” is misspelled on line 7 of Claim 15; "region" on line 10 should be changed to "space;" and “fluid connecting space” on line 13 should be changed to “fluid collecting space.” The term “region” should be changed to “space” on line 4 of Claim 16. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 3-4 & 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wesseler (US 5,534,228) in view of Tingey et al. (US 2002/0168530, "Tingey").

With regard to Claim 10, Wesseler teaches a closure device (as shown in Fig. 4, which is capable for connection to a vessel and act as a closure device) for a container, comprising a filling device (3, 3A, 3B, & 4 combined) that can be attached to an opening of the container and a closure means (4 and 3) that is attached to the filling device in such a way that the opening of the container is sealed if the filling device is attached to the opening. However, Wesseler does not teach that the closure means is at least partially coated with polytetrafluoroethylene on one side that is accessible from outside the container in the assembled state of the filling device on the container. Tingey teaches providing a coating of polytetrafluoroethylene (1) on the outside surface of a closure means (20) of a closure device (10). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Wesseler with Tingey for the purpose of allowing a smoother fit when the closure means is pushed in.

With regard to Claims 3-4, Wesseler also teaches that the closure means is a membrane or septum.

6. Claims 2-4, 6-10, & 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 2002/0130100) in view of Tingey.

With regard to Claim 10, Smith teaches a closure device (40) for a container, comprising:

a filling device that can be attached to an opening of the container;

a closure means (42, 73A, or 140) that is attached to the filling device in such a way that the opening of the container is sealed if the filling device is attached to the opening; and

a collecting space (i.e. space above 73A in Fig. 6B) for receiving a fluid that can be introduced into the collecting space.

Smith does not teach that the collecting space receives fluid *through* the closure means. However, mere rearrangement of parts (i.e. moving the closure means 73A of Fig. 6B from its current position to a little higher up in the collecting space) would require only routine skills in the art. The collecting space would then receive fluid *through* the closure means and the conical wall (in touch with interior wall of the container) outlining the collecting space helps to direct the fluid toward the middle of the container.

Smith also does not teach that the closure means is at least partially coated with polytetrafluoroethylene on one side that is accessible from *outside* the container. However, Smith teaches that the closure means can be hydrophobic (which will cause the liquid to bead rather than spread, just like the instant invention as explained by the Applicant on page 10 third paragraph of Amendment filed on 12/2/2008) and manufactured from polytetrafluoroethylene (PTFE, [0114]) but does not suggest that the PTFE is *coated* on the *outside* surface.

Tingey teaches a closure device (10) having closure means (20) with a coating of PTFE (1) on a surface accessible from outside a container in the assembled state. It would have been obvious to one of ordinary skill in the art at the time of the invention to

modify Smith with Tingey for the purpose of reducing the amount of liquid sticking to the closure means.

With regard to Claim 3, Smith also teaches that the closure means is a membrane.

With regard to Claim 4, Smith also teaches that the closure means is a membrane or septum ([0086], "diaphragm 42").

With regard to Claim 2, Smith also teaches that the membrane or septum is configured to be pierced by a needle tip (see Fig. 6B) through which fluid is introduced into the collecting space and to seal itself ([0085]) when the needle tip is removed.

With regard to Claim 6, after the modification of Smith with the PTFE coating of Tingey as explained above, the coating would cover the region of the side of the membrane or septum that is provided for piercing with the needle tip such that the PTFE coating is pierced by the needle tip.

With regard to Claim 7, Tingey also teaches that the closure means can be made of silicone. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Smith with Tingey for the purpose of employing a widely available and relatively inert material for containing medical or biological liquids.

With regard to Claim 8, Smith also teaches that the closure means comprises a closure structure formed of soft material (diaphragm 73A) and a needle guide (see Fig. 6B the parts that touches the interior wall of the container 50 and holds diaphragm 73A in place) that encloses the closure structure and a portion of a needle tip receiving side of the closure structure, the needle guide being formed of a hard material

(polypropylene or polyethylene, [0086] last sentence) and defining a funnel-shaped opening (the slight taper is broadly interpreted to be a funnel shape) which directs the needle tip toward the closure structure. In the lack of definition for what “good adhesive properties” means, Smith’s disclosure of the closure means being able reseal, as in [0085], and the periphery of the diaphragm 42 sealing against the interior wall of the container, as in [0086], are both considered to be exhibition of "good adhesive properties."

With regard to Claim 9, Smith also teaches that the closure device further includes a Luer closure device that extends from the collecting space (the parts of the closure device that touches the inner surface wall of the container forms a Luer fit with the container and is therefore considered to be a Luer closure device, see Fig. 6B) and configured to be attached to the opening of the container.

With regard to Claims 13 & 14, Smith teaches a closure device which closes an opening of a point of care testing container (a microcentrifuge tube can be used in body fluids analytics processes) which receives bodily fluids via a needle and which testing container is configured to be received in a point of care testing device, the closure device comprising:

a structure which defines a collecting space (space above 73A, Fig. 6B) for receiving the bodily fluids;

a connecting structure (in touch with the inner surface wall of the container) which extends from the collecting space defining structure, the connecting

structure being configured to connect with the opening of the point of care testing container;

a closure structure (73A) which closes an end of the collecting space opposite to the connecting structure (broadly interpreted to be "opposite the rim of the container opening that touches the connecting structure"), the closure structure being configured to be penetrated by the needle and to seal when the needle is withdrawn;

Smith does not expressly teach that there is a low wettability *coating* on at least a portion of the closure structure but that the closure structure is hydrophobic.

Tingey teaches a closure device (10) having closure means (20) with a coating of PTFE (1) on a surface accessible from outside a container in the assembled state. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Smith with Tingey for the purpose of reducing the amount of liquid sticking to the closure means.

With regard to Claim 15, Smith teaches a closure device comprising:

a structure that defines a fluid collecting space (space above 73A, Fig. 6B);

a connecting structure (in touch with the inner wall surface of the container) which extends from and defines an outlet to the fluid collecting space, the connecting structure being configured to be connected to an opening of a container such that fluid drains from the collecting space into the container;

a closure structure (73A) which closes an end of the fluid collecting space opposite to the connecting structure;

wherein the closure structure is configured to be penetrated by a tip of a needle which delivers the fluid and to seal against the fluid leaving through the closure structure.

Smith does not teach a polytetrafluoroethylene coating or that the fluid collecting space receives fluid after the needle penetrates the closure structure. However, as explained under Claim 10, mere rearrangement of parts (i.e. moving the closure means 73A of Fig. 6B from its current position to a little higher up in the collecting space) would require only routine skills in the art.

Tingey teaches a closure device (10) having closure means (20) with a coating of PTFE (1) on a surface accessible from outside a container in the assembled state. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Smith with Tingey for the purpose of reducing the amount of liquid sticking to the closure means.

With regard to Claim 16, Smith teaches a tapered needle guide but does not expressly teach that it is disposed opposite to the fluid collection space. However, merely rearranging the closure structure (73A) upward a little (much like diaphragm 121 being located halfway in a tubular structure in Fig. 9D) would give the closure device both a fluid collecting space that is under the closure structure and a tapered needle guide that is disposed opposite to the fluid collecting space (note that by this modification the connecting structure of Claim 15 becomes the lowest point at which it

contacts the inner wall surface of the container). It would have been obvious to one of ordinary skill in the art to make the rearrangement for the purpose of having a fluid collecting space that directs fluid flow towards the center of the container.

With regard to Claim 17, Tingey also teaches that the closure means (20) has a cross-section (both above and below the neck region 12) that is larger than a cross-section of the connecting structure (the wall surrounding space 17). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Smith by elongating the closure device upward from the container so that the closure means does not need to sit within the container and that the closure means can be made larger to allow better channeling of the needle and the fluid into the container.

With regard to Claim 18, Tingey also teaches that the closure means can be made of silicone. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Smith with Tingey for the purpose of employing a widely available and relatively inert material for containing medical or biological liquids.

With regard to Claim 19, Smith also teaches a container (50) connected to the connecting structure such that the fluid received in the fluid collecting space drains into the container.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith and Tingey as applied to claim 8 above, and further in view of Healy (US 5,425,465). Smith and Tingey do not teach that the closure means is a duck-bill valve although Smith teaches a one-way valve (90) which serves to wipe a pipette or needle clean as it is withdrawn from the container. Healy teaches a duck-bill valve (Fig. 3A) as a closure

means for a medical container. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Smith and Tingey with Healy for the purpose of preventing backflow of liquid from the container.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith and Tingey as applied to claim 8 above, and further in view of Cox et al. (US 4,935,010, "Cox"). Smith and Tingey do not expressly teach PTFE coated on the funnel-shaped surface. Cox teaches a funnel shaped needle guide (62) with PTFE at the surface to facilitate the needle to slide to the desired position. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Smith and Tingey with Cox for the purpose of helping to slide the needle to the membrane for puncture.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith and Tingey as applied to claim 15 above, and further in view of Schall et al. (US 6,699,677, "Schall"). Smith also teaches that the fluids are bodily fluids but neither Smith nor Tingey expressly teaches that the container is a point of care testing container that is configured to be received in a point of care testing system which analyzes the bodily fluids at a point of patient care. Schall teaches putting a ligand in a microcentrifuge tube and using an automated fluorometric system (which can be used in a doctor's office since it is an automated system) to perform the analysis. In the lack of an exact definition for the structure of a point of care testing container and a point of care testing system, the microcentrifuge of Smith is considered to be appropriate for point of care testing such as the method and system disclosed in Schall. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify

Smith and Tingey with Schall for the purpose of allowing the patient and the practitioner to diagnose a simple medical condition quickly and safely.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Several references are provided on the PTO-892 form that are relevant to the instant invention, in addition to the above cited references.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848.

The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761